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Assessment of the effect of perindopril orodispersible tablet at the dose of 0.150 mg/kg /day on muscular and myocardic functions in the early stage of Duchenne Muscular Dystrophy: a two-year, double-blind, randomised, placebo-controlled study

Submission date	Recruitment status	[_] Prospectively registered
16/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2020	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-003856-32

Protocol serial number

CL3-90652-004

Study information

Scientific Title
Assessment of the effect of perindopril orodispersible tablet at the dose of 0.150 mg/kg/day on muscular and myocardic functions in the early stage of Duchenne Muscular Dystrophy: a two-year, double-blind, randomised, placebo-controlled study

Study objectives
Effect on peripheral muscular function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Double-blind randomised placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Duchenne Muscular Dystrophy

Interventions
Perindopril orodispersible tablet 0.150 mg/kg/day versus placebo for two years.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perindopril

Primary outcome(s)
Six-minute walking distance, evaluated each 6 months

Key secondary outcome(s))
1. Other muscular tests
2. Echocardiography
3. Respiratory function assessment

Evaluated at inclusion visit and end-of-study visit

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Children, less than 7 years old with Duchenne Muscular Dystrophy and able to complete a 6-minute walk test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
7 years

Sex
Male

Total final enrolment
40

Key exclusion criteria
1. Long term treatment with corticoids
2. Treatment with ACE inhibitors or AT1 antagonists

Date of first enrolment
01/02/2009

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
France

Study participating centre

Groupe hospitalier Necker - Enfants Malades
Paris Cedex 15
France
75743

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			21/04/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes